United States Department of Agriculture
Animal and Plant Health Inspection Service
Center for Veterinary Biologics
P. O. Box 844
Ames, IA 50010

1. Reagent Name: *Clostridium septicum* Antitoxin

2. Strain or Source: Not Applicable

3. Lot Number: IRP 600

4. Fill Date: June 28, 2012

5. Expiration Date: No expiration date has been assigned to this product because *C. septicum* alpha antitoxin has demonstrated over time to be very stable if properly stored. The stability of this reagent will be routinely monitored by the Bacteriology Laboratory, Center for Veterinary Biologics.

Precautions: This reagent does not present a hazard to laboratory personnel who manipulate the antitoxin provided standard laboratory practices are followed.

6. Intended Use: IRP 600 serves as the standard antitoxin when determining *C. septicum* alpha antitoxin values using a toxin neutralization (TN) test in mice.

7. Instructions for Use: *C. septicum* antitoxin IRP 600 contains 120 units of antitoxin. One mL of standard antitoxin containing 1.0 antitoxin unit per mL (AU/mL) is used when determining the antitoxin content of serum from animals vaccinated with product containing *C. septicum toxoid.*

To conduct TN tests in mice at the 1 AU/mL level, dilute IRP 600 1:120. Prepare the dilution by transferring 1.0 mL of IRP 600 to 9 mL of diluent and transferring 1.0 mL of the 1:10 dilution to 11 mL of diluent.

8. Test of Reagent:

Determination of antitoxin titer – The antitoxin titer of IRP 600 was determined by injecting mice intravenously with 0.5 mL of diluted antitoxin mixed with 1.0 L+ dose of toxin (the smallest amount of toxin which, when mixed with 1.0 unit of antitoxin, causes death in at least 80% of the animals within 72 hours) and 1.0 Lo dose of toxin (the largest amount of toxin which, when mixed with 1.0 unit of antitoxin, causes no deaths in any of the animals within 72 hours). The antitoxin titer was confirmed by comparing the results of mice injected with toxin-antitoxin mixtures containing 1.0 mL of IRP 600 possessing 1.0 unit of antitoxin to the results of mice

injected with toxin-antitoxin mixtures containing 1.0 mL of *C. septicum* International antitoxin possessing 1.0 AU/mL.

Sterility test – Ten vials of IRP 600 were tested for sterility according to 9CFR 113.26. The antitoxin was found to be free of viable bacteria and fungi.

9. Container Size, Type, Weight, or Volume: 2mL glass vials containing 1.3mL of antitoxin.

10. Storage Conditions: Store at -70°C or lower.

11. CVB Technical Contact: Bacteriology Section, Center for Veterinary Biologics, (515) 337-6140 or FAX (515) 337-7673.

12. Origin and Passage History: Not applicable.

13. Method of Preparation: Two-year-old ponies weighing 400 to 500 pounds with no history of Clostridial vaccinations received multiple injections of *C. septicum* toxoid and toxin during a 9-month period. The serum was passed through a sterile Millipore filtration unit containing a 0.22-µm membrane. The ponies used for antitoxin preparation tested negative on serological tests for Equine Infectious Anemia, Piroplasmosis, Dourine, Glanders and Brucellosis.

14. Other:

Reagent orders and feedback should be sent *including phone number* to the following email address: CVB@aphis.usda.gov

Reagent orders forms (APHIS 2018) are available from:
http://www.aphis.usda.gov/animalhealth/cvb_forms

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